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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,198	11/07/2006	Kumar Visvanathan	007193	7410
The McCallum	7590 10/15/200 Law Firm	EXAMINER		
132 Kolar Ct			BOESEN, AGNIESZKA	
Erle, CO 80516	1		ART UNIT	PAPER NUMBER
			1648	-
			MAIL DATE	DELIVERY MODE
			10/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/550,198	VISVANATHAN ET AL.				
Office Action Summary	Examiner	Art Unit				
	AGNIESZKA BOESEN	1648				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing eamed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE.	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on July 1	7 <u>, 2009</u> .					
2a) This action is <b>FINAL</b> . 2b) This action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 65-136 is/are pending in the application 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 65-136 are subject to restriction and/or	wn from consideration.					
Application Papers						
9)☐ The specification is objected to by the Examine	r.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau. * See the attached detailed Office action for a list.	s have been received. s have been received in Applicati ity documents have been receive I (PCT Rule 17.2(a)).	on No ed in this National Stage				
Attachment(s)						
1) Notice of References Cited (PTO-892)		4) Interview Summary (PTO-413) Paper No(s)/Mail Date				
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	5) Notice of Informal P  6) Other:					

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#### DETAILED ACTION

Applicant's election of group II, claims 81-92 is acknowledged. New claims 137 and 138 read on the elected group II. Claims 1-80 and 93-136 have been canceled.

Upon further consideration the claims are subject to the species election requirement.

Any inconvenience is regretted.

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group II, claim(s) 81-92, 137 and 138 drawn to a method for monitoring a response to a therapeutic protocol to prevent infection by a pathogenic agent and to prevent the development of a disease condition comprising determining the level of a cell surface marker selected from the group consisting of Toll-like receptors.

#### Species election

This application contains claims directed to the following patentably distinct species:

#### One pathogenic agent from:

Salmonella, Escherichia, Klebsiella, Pasteurella, Bacillus, Clostridium, Corynebacterium, Mycoplasma, Ureaplasma, Actinomyces, Mycobaeterium, Chlamydia, Chlamydophila, Leptospira, Spirochaeta, Borrelia, Treponema, Pseudomonas, Burkholderia, Dichelobacter, Haemophilus, Ralstonia, Xanthomonas, Moraxella, Acinetobacter, Branhamella, Kingella,

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Erwinia, Enterobacter, Arozona, Citrobacter, Proteus, Providencia, Yersinia, Shigella, Edwardsietla, Vibrio, Rickettsia, Coxiella, Ehrlichia, Arcobacteria, Peptostreptococcus, Candida[[.]]~ Aspergiilus, Trichomonas, Bacterioides, Coccidiomyces, Pneumoeystis, Cryptosporidium, Porphyromonas, Actinobacillus, Lactococcus, Laetobacillua, Zymononas, Saccharomyces, Propionibacterium, Streptomyces, Penicillum, Neisseria, Staphylococcus, Campylobacter, Streptococcus, Enterococcus, Helicobacter, human immunodeficiency virus (HW), Varicella-Zoster virus (VZV), herpes simplex virus (HSV), human papillomavirus (HPV), Hepatitis B virus (HBV), Hepatitis A virus (HAV), rhinovirus, echovirus, Coxsackievirus, eytomegalovirus, flavivirus, Ebola virus, paramyxovirus, influenza virus, enterovirus, Epstein-Ban- virus, Marburg virus, polio virus, rabies virus, rubella virus, smallpox virus, rubeola virus, vaccina virus, adenovirus, rotavirus: Hepatitis C virus (HCV) and Hepatitis B vires (HBV).

### One toll like receptor:

# TLR-2 or TLR-4

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 81-92, 137 and 138 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search

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queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include

(i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on Monday to Friday from 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/ Examiner, Art Unit 1648